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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/695,189 | 10/27/2003 | Joo W. Kim | 632-001 | 4297 |

7590 11/24/2006

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/695,189 | KIM, JOO W. | |
| | Examiner | Art Unit | |
| | David P. Stitzel, Esq. | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14,16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## OFFICIAL ACTION

### *Acknowledgment of Receipt*

Receipt of the Applicant's Response and Amendment, which was filed on August 23, 2006, in response to the Official Action dated June 2, 2006, is acknowledged.

### *Status of Claims*

Claims 1-11 and 19-31 were withdrawn, claims 12, 13, 15 and 17 were canceled, and claims 14 and 16 were amended, by the aforementioned Amendment. As a result, claims 14, 16 and 18 are therefore examined herein on the merits for patentability.

### *Specification Objection*

1. The aforementioned Amendment is objected to under 35 U.S.C. § 132(a) because it introduces new matter into the disclosure. More specifically, 35 U.S.C. § 132(a) states that no amendment shall introduce new matter into the original disclosure of the invention. The newly added material in paragraph [0052] of the instant specification that is not supported by the original disclosure is as follows: "Herein, the term 'essentially free of propylene glycol' means containing no more than trace amounts of propylene glycol, none of which were manually added to the formulations." Applicant is required to cancel the new matter in the Response to this Official Action.

### *Claim Rejections - 35 U.S.C. § 112, Second Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 18 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

With respect to claim 18, confusion exists because the claim recitation of "'essentially free' of propylene glycol" is in direct contradiction to what is explicitly disclosed in the specification as originally filed in that said specification is replete with statements that the composition of the instant application is "propylene glycol free," which is reasonably understood by those of ordinary skill in the art to mean that propylene glycol is completely absent from the composition of the instant application, that is, that said composition contains absolutely no propylene glycol whatsoever including trace amounts thereof. See e.g., [0013], [0014], [0015], [0016], original claims 1 and 2, of U.S. Pre-Grant Patent Application Publication 2005/0089488 (the Kim '488 publication), which is the published version of the instant application. Furthermore, the disclosure of the specification as originally filed ([0003], [0047]-[0052], Tables 13 and 14) explicitly distinguishes the composition of the instant application (C and D) from a prior art composition (B) by illustrating that unlike the prior art composition, which contains propylene glycol and thereby causes skin irritation, the composition of the instant application is propylene glycol free and therefore does not cause skin irritation.

Confusion also exists as to what constitutes "'essentially free' of propylene glycol?" More specifically, the phrase "essentially free" is a relative term that renders claim 18 indefinite. The phrase "essentially free" is not defined within said claim, the instant specification does not appear to provide a standard for ascertaining the requisite degree of what constitutes "'essentially free' of propylene glycol," and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention as "'essentially free' of propylene glycol" may in some instance mean less than 0.1

wt. % propylene glycol, whereas in other instances "essentially free" may constitute less than 1 part per billion propylene glycol, which vary vastly in claim scope.

Applicant is requested to either cancel claim 18, or delete the phrase "essentially free of propylene glycol" and add in place thereof "propylene glycol free," which has support in the specification as originally filed, as discussed hereinabove.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 12-18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,516,510 (hereinafter the Beilfuss '510 patent) in view of U.S. Patent 5,736,574 (hereinafter the Burnier '574 patent) and Madhavan BN, "Final Report on the Safety Assessment of Bisabolol," International Journal of Toxicology, Volume 18, Supplement 3, pp. 33-40 (1999) (hereinafter the

Madhavan publication) is hereby withdrawn in light of the cancellation of claims 12, 13, 15 and 17, and amendment to claims 14 and 16.

2. Claims 14, 16 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Beilfuss '510 patent in view of the Burnier '574 patent and the Madhavan publication.

With respect to claims 14, 16 and 18 of the instant application, the Beilfuss '510 patent teaches a synergistic antimicrobial deodorant composition comprising: one or more glycerin monoalkyl ethers, namely 2-ethylhexylglycerin (a.k.a., 3-[(2-ethylhexyl)oxy]-1,2-propanediol, 1-(2-ethylhexyl) glyceryl ether, and Sensiva), present in an effective amount of from about 0.01 wt. % to about 20 wt. %; and an effective amount of *one or more sesquiterpene alcohols*, namely farnesol; present in an effective amount of from about 50:1 to about 1:50 based on a ratio of said 2-ethylhexylglycerin to said farnesol sesquiterpene alcohol; wherein said synergistic antimicrobial composition exhibits efficacious bactericidal properties against not only gram-negative bacteria (i.e., *Proteus mirabilis*, *Klebsiella pneumoniae*, and *Enterobacter gergoviae*), but also odor causing gram-positive bacteria (i.e., *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Micrococcus luteus*) (abstract; columns 1-5; claims 1-6).

The Beilfuss '510 patent does not explicitly teach that said synergistic antimicrobial composition is essentially free of propylene glycol, as claimed in claim 18.

However, Burnier '574 patent teaches a synergistic antimicrobial deodorant composition comprising: an effective amount of one or more glyceryl monoalkyl ethers, namely 2-ethylhexylglycerin (a.k.a., 3-[(2-ethylhexyl)oxy]-1,2-propanediol, 1-(2-ethylhexyl) glyceryl ether, and Sensiva); and *any other additional ingredient typically used in cosmetic and dermatological compositions*; wherein said synergistic antimicrobial composition exhibits efficacious bactericidal

properties against not only gram-negative bacteria (i.e., *Escherichia coli*, and *Pseudomonas aeruginosa*), but also odor causing gram-positive bacteria (i.e., *Staphylococcus aureus*, and *Enterobacter faecalis*); wherein *incorporation of propylene glycol within said synergistic antimicrobial deodorant composition is explicitly discouraged* because propylene glycol was known to those of ordinary skill in the art at the time the instant application was filed to cause skin irritations and skin allergies (column 1, lines 23-29; column 3, lines 19-32, 36-44 and 53-61; column 4, lines 2, 3 and 20-23; claims 1 and 21).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed Not to incorporate propylene glycol into the synergistic antimicrobial deodorant composition of the Beilfuss '510 patent, so as to avoid adverse skin irritations and skin allergies, as taught by the Burnier '574 patent. One of ordinary skill in the art would have been motivated Not to incorporate propylene glycol into the synergistic antimicrobial deodorant composition of the Beilfuss '510 patent, since the Burnier '574 patent explicitly discourages the incorporation of propylene glycol into synergistic antimicrobial deodorant compositions because propylene glycol was known to those of ordinary skill in the art at the time the instant application was filed to cause skin irritations and skin allergies.

In addition, the Beilfuss '510 patent does not explicitly teach said synergistic antimicrobial deodorant composition comprises α-bisabolol as one or more of said sesquiterpene alcohols, as claimed in claim 14.

However, the Madhavan publication teaches an antimicrobial deodorant composition comprising an *α-bisabolol sesquiterpene alcohol* present in an effective amount of from about 0.01 wt. % to about 1 wt. %; wherein said α-bisabolol sesquiterpene alcohol *not only exhibits bacteriotoxic effects against gram-negative bacteria* (i.e., *Salmonella typhimurium*), *but is also typically used in*

*cosmetic and dermatological compositions* as a skin conditioning agent, an anti-inflammatory agent and an epidermal penetration enhancer (page 33, column 2, lines 8-16 and 39-40; page 35, Table 1; page 37, column 1, lines 40-42; page 38, column 1, last paragraph; page 39, column 1, lines 8-11 and 46-50; page 38, column 2, lines 1-3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the synergistic antimicrobial deodorant composition of the Beilfuss '510 patent, by incorporating either in addition to, or in place of, the farnesol sesquiterpene alcohol taught therein, the α-bisabolol sesquiterpene alcohol of the Madhavan publication. One of ordinary skill in the art would have been motivated to incorporate said α-bisabolol sesquiterpene alcohol either in addition to, or in place of, the farnesol sesquiterpene alcohol, since the Beilfuss '510 patent explicitly teaches incorporating one or more naturally occurring antimicrobial agents, such as sesquiterpene alcohols, into said synergistic antimicrobial deodorant composition, and the Madhavan publication teaches that said α-bisabolol is a sesquiterpene alcohol that *exhibits bacteriotoxic effects against gram-negative bacteria* (i.e., *Salmonella typhimurium*).

Furthermore, it would have also been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the synergistic antimicrobial deodorant composition of the Beilfuss '510 patent by incorporating therein any other additional ingredient typically used in cosmetic and dermatological compositions, as taught by the Burnier '574 patent, such as the α-bisabolol sesquiterpene alcohol taught in the Madhavan publication, since the Madhavan publication teaches that said α-bisabolol sesquiterpene alcohol is typically used in cosmetic and dermatological compositions, not only as a bacteriotoxic agent, but also as a skin conditioning agent, an anti-inflammatory agent and an epidermal penetration enhancer.

***Remarks***

The following is a prior art scientific journal article publication made of record and considered pertinent to the Applicant's disclosure, but is not however currently relied upon in construing the claim rejections as set forth herein:

- Moura NF, Simionatto E, Porto C, Hoelzel SCS, Dessoy ECS, Zanatta N, Morel AF, "Quinoline Alkaloids, Coumarins and Volatile Constituents of *Helietta longifoliata*," Plant Med, Vol. 68, pp. 631-634 (2002) (an essential oil comprising 80 wt. % antimicrobial sesquiterpenes, and more specifically approximately 8 wt. % antibacterial α-bisabolol and epi-α-bisabolol as major constituents therein, which exhibited efficacious antibacterial properties against not only gram-negative bacteria (i.e., *Klebsiella pneumoniae*, *Salmonella setubal*, and *Escherichia coli*), but also odor causing gram-positive bacteria (i.e., *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Micrococcus luteus*).

***Examiner's Response to Applicant's Remarks***

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered in light of the claims as currently amended, they are not persuasive. Applicant's claim amendments canceling claims 12, 13, 15 and 17 and amending claims 14 and 16 necessitated the new grounds of rejection as set forth hereinabove.

1. 35 U.S.C. § 112, second paragraph, rejection of claim 18 as being indefinite.

Applicant argues on pages 7 and 8 that the recitation of "'essentially free' of propylene glycol" does not render claim 18 indefinite. In response to Applicant's arguments, confusion exists because the claim recitation of "'essentially free' of propylene glycol" is in direct contradiction to what is explicitly disclosed in the specification as originally filed in that said specification is replete with statements that the composition of the instant application is "propylene glycol free," which is reasonably understood by those of ordinary skill in the art to mean that propylene glycol is completely absent from the composition of the instant application, that is, that said composition contains absolutely no propylene glycol whatsoever including trace amounts thereof. See e.g., [0013], [0014],

[0015], [0016], original claims 1 and 2, of U.S. Pre-Grant Patent Application Publication 2005/0089488 (the Kim '488 publication), which is the published version of the instant application. Furthermore, the disclosure of the specification as originally filed ([0003], [0047]-[0052], Tables 13 and 14) explicitly distinguishes the composition of the instant application (C and D) from a prior art composition (B) by illustrating that unlike the prior art composition, which contains propylene glycol and thereby causes skin irritation, the composition of the instant application is propylene glycol free and therefore does not cause skin irritation.

In addition, the phrase "essentially free" is a relative term that renders claim 18 indefinite because the phrase "essentially free" is not defined within said claim, the instant specification does not appear to provide a standard for ascertaining the requisite degree of what constitutes "'essentially free' of propylene glycol," and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention. It should also be mentioned that Applicant's attempt to clearly define what constitutes "'essentially free' of propylene glycol" by amending the original disclosure with the following statement: "Herein, the term 'essentially free of propylene glycol' means containing no more than trace amounts of propylene glycol, none of which were manually added to the formulations," not only constitutes the addition of new matter (see the Specification Objection hereinabove), but also presents additional ambiguity since the original disclosure does not clearly define what constitutes "no more than 'trace amounts' of propylene glycol." That is, "trace amounts" may in some instances constitute less than 0.1 wt. %, whereas in other instances "trace amounts" may constitute less than 1 part per billion, which vary vastly in claim scope. *Moreover, what may be considered to be a "trace amount" from a chemical formulation standpoint, may not necessarily be tantamount to what is considered to be a "trace amount" with respect to an immunological response associated with skin irritation.*

2. U.S.C. § 103(a) rejection of claims 14, 16 and 18 based on the Beilfuss '510 patent in view of the Burnier '574 patent and the Madhavan publication.

Applicant argues on pages 9 and 10 of the aforementioned Response, that because the Madhavan publication teaches that "α-bisabolol was negative in bacterial and mammalian genotoxicity tests," the Madhavan publication stands for the proposition that α-bisabolol is in fact not bacteriotoxic, as instantly claimed. In response to Applicant's arguments, while it is true that the Madhavan publication teaches that α-bisabolol was negative in bacterial and mammalian genotoxicity tests (abstract) and that α-bisabolol tested negative with respect to mutagenicity assays (page 38, column 1, last paragraph; page 38, column 2, lines 1 and 2), the Madhavan publication explicitly states that "a bacteriotoxic effect was noted [with α-bisabolol]" (page 38, column 1, last two lines of the last paragraph). Applicant's arguments are fundamentally flawed in that Applicant equivocates genotoxicity and mutagenicity with bacteriotoxicity. Genotoxins and mutagens are readily known by those of ordinary skill in the art as being an agent (e.g., a chemical, UV light, or radioactive element) that damages genetic material (i.e., DNA) in cells, thereby inducing, or increasing the frequency of, mutations and/or cancer in organisms. In contrast, bacteriotoxins are readily known by those of ordinary skill in the art as being an agent that destroys and/or inhibits the growth of bacteria.

Applicant argues on pages 10 and 11 of the aforementioned Response, that none of the cited prior art references teach or suggest, either individually or in combination, a synergistic antimicrobial combination of a glycerin monoalkyl ether (e.g., 2-ethylhexylglycerin) and α-bisabolol. In response to Applicant's arguments, although the Beilfuss '510 patent teaches a synergistic antimicrobial deodorant composition comprising: one or more glycerin monoalkyl ethers, namely 2-ethylhexylglycerin; and *one or more sesquiterpene alcohols*, the Beilfuss '510 patent does not explicitly α-bisabolol as being one or more of said sesquiterpene alcohols.

However, the Madhavan publication teaches a synergistic antimicrobial deodorant composition comprising an *α-bisabolol sesquiterpene alcohol* that *exhibits bacteriotoxic effects against gram-negative bacteria* (i.e., *Salmonella typhimurium*). Based on the aforementioned teachings of the cited prior art references, it would have been prima facie obvious, and one of ordinary skill in the art would have been motivated, to incorporate the *α-bisabolol sesquiterpene alcohol of the* Madhavan publication as being one or more of said *sesquiterpene alcohols of* the Beilfuss '510 patent.

However, the Burnier '574 patent teaches a synergistic antimicrobial deodorant composition comprising: an effective amount of one or more glyceryl monoalkyl ethers (e.g., 2-ethylhexylglycerin); and *any other additional ingredient typically used in cosmetic and dermatological compositions.* However, the Madhavan publication also teaches that said α-bisabolol sesquiterpene alcohol is typically used in cosmetic and dermatological compositions, not only as a bacteriotoxic agent, but also as a skin conditioning agent, an anti-inflammatory agent and an epidermal penetration enhancer. Based on the aforementioned teachings of the cited prior art references, it would have been prima facie obvious, and one of ordinary skill in the art would have been motivated, to incorporate the *α-bisabolol sesquiterpene alcohol of the* Madhavan publication as being one or more of said *sesquiterpene alcohols of* the Beilfuss '510 patent, especially since the Madhavan publication teaches that *α-bisabolol sesquiterpene alcohol* is a skin conditioning agent, an anti-inflammatory agent and an epidermal penetration enhancer, which is typically used in cosmetic and dermatological compositions, as taught in the Burnier '574 patent.

### *Conclusion*

Applicant's claim amendments canceling claims 12, 13, 15 and 17 and amending claims 14 and 16 necessitated the new grounds of rejection as set forth hereinabove. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Contact Information*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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